

EXHIBIT Q

Long-Term Results of Burch Colposuspension

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Key Words

Urinary incontinence · Burch colposuspension · Cure rate · Perineal ultrasonography

Abstract

The study included 220 women who had undergone Burch colposuspension. Group I (65 women) was studied prospectively and the mean follow-up was 1.5 years. Group II (155 women) was studied retrospectively and the mean follow-up was 4.5 years. The cure rate was 87.7% in group I and 77.4% in group II. The cure rate was significantly higher following the primary procedure than the secondary procedure. At follow-up, late complications in 220 women were: cystocele in 18; rectocele in 32; enterocele in 35; dyspareunia in 6, and groin or suprapubic pain in 15. In group I, of the 11 women with detrusor instability preoperatively, 10 were cured and in 1 detrusor instability persisted postoperatively. Two women had de novo detrusor instability. In conclusion, the cure rate of Burch colposuspension is satisfactory, although it declines a little with time. Women who had previous anti-incontinence surgery have a greater probability of recurrence. The procedure elevates the bladder neck into the abdominal cavity and stabilizes it. Surgical failure is related to inadequate elevation and stabilization of the bladder neck.

Introduction

Genuine stress urinary incontinence (GSI) is the most common type of female urinary incontinence. Despite advances in conservative treatment, the most effective therapy of severe GSI is surgery. Almost 200 various operations have been described for the treatment of GSI [1]. Selection of an operation is based on accurate diagnosis of the type of stress incontinence, which is generally categorized as bladder neck (BN) hypermobility (type I and II GSI) and intrinsic sphincter deficiency (type III stress incontinence). Patients with type I/II GSI have been treated with anterior colporrhaphy, needle techniques or retropubic procedures such as the Marshall-Marchetti-Krantz and Burch colposuspension, while pubovaginal sling has been reserved for correction of patients with type III incontinence. Burch colposuspension remains one of the most popular and successful operations for GSI caused by BN hypermobility. However, the studies which reported cure rates of Burch colposuspension are usually performed on a small number of patients and reported short-term follow-ups. Long-term evaluation is important because of the time-dependent decline in cure rates and its late complications. Our purpose is to review late complications and the long-term outcome of the Burch colposuspension procedure.

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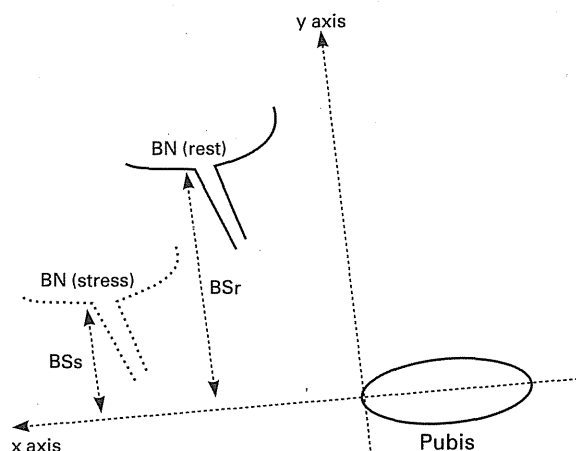


Fig. 1. Evaluation of bladder neck mobility on perineal ultrasonography. BN = Bladder neck; BSr = distance between the bladder neck and x axis at rest; BSs = distance between the bladder neck and x axis during stress. Δ BS = BSr – BSs (bladder neck mobility/descent).

Materials and Methods

We retrospectively reviewed the hospital records of 360 Burch colposuspension procedures from 1994 to 1999 in two centers, and the intraoperative and early postoperative complications were published [2]. The same women were invited to the hospitals to assess late postoperative complications and outcome. The women had been prospectively assessed in both centers since 1998, and in the second center the women were assessed retrospectively until 1998. The study consisted of 220 women seen at the hospitals and for whom the records were available. Group I consisted of women who had been evaluated prospectively, and group II were women evaluated retrospectively. Group I included 65 women who had undergone operations from 1998 to 1999 (mean follow-up 1.5 years), and group II included 155 women who had undergone operations from 1994 to 1997 (mean follow-up 4.5 years). The study did not include intraoperative and early postoperative complications which have been published [2].

All women underwent several investigations: history; complete physical and pelvic examination; urine culture; stress tests for loss of urine with a full bladder and coughing, the sound of running water in the standing and in the lithotomy positions, and the stress of heel bouncing. While group I had undergone multichannel urodynamic studies preoperatively, group II women had not; they had mostly been evaluated clinically. Urodynamic studies were performed postoperatively only on patients who suffered from urinary incontinence in both groups.

In group I women, the BN was evaluated by perineal ultrasonography preoperatively and postoperatively, while only patients with urinary incontinence were evaluated by perineal ultrasonography in group II postoperatively. Perineal ultrasonography was performed to assess the position and mobility of the BN [3]. We used a 3.5-MHz curvilinear transducer covered with a stretch film, which was placed

Table 1. Patients' characteristics at operation

Age, years	47.80 ± 5.90
Parity	4.75 ± 2.29
BMI, kg/m ²	29.27 ± 3.90
Postmenopausal	72 (32.7%)
Previous incontinence surgery	29 (13.2%)

Table 2. Outcome of operation at follow up

	Group I (n = 65)	Group II (n = 155)
Surgical failure	4 (6.2%)	19 (12.2%)
Detrusor instability	2 (3.1%)	5 (3.2%)
Mixed incontinence (surgical failure + DI)	2 (3.1%)	11 (7.1%)
Anatomical cure rate	59 (90.8%)	125 (80.6%)
Symptom-free cure rate	57 (87.7%)	120 (77.4%)

on the sagittal axis of the perineum following sterile gel application in the supine position. The women had drunk sufficient water to sense the fullness of their bladders. The image was frozen and placed on one side of the screen as soon as the symphysis pubis, the bladder, the BN and the urethra were all visualized. The measurements were made taking the inferior tip of symphysis pubis as a reference point. BS was defined as the distance between BN and the line passing through the inferior border of symphysis pubis (x axis). Next, the patient was asked to perform Valsalva maneuvers several times and the image was frozen and placed on the other half of the screen when the greatest BN mobility was seen. The BS distance was measured again and it was taken as the stress value. Cephalocaudal mobility of the BN (BN descent, Δ BS) was calculated by subtracting the BS of stress from the BS of the other values (in women where the BN was found to be below the inferior tip of the symphysis pubis, the two values were added instead of being subtracted; fig. 1). All measurements were taken in millimeters by the first author. In incontinent women, if the postoperative Δ BS was >10 mm it was considered a surgical failure.

Statistical analysis was performed with the statistical package for the social sciences (SPSS 7.5 for Windows) on a computer. Student's t test and χ^2 test were used for comparison. A p value of ≤ 0.05 was considered significant.

Results

The study included 220 women, of whom 155 (group II) had undergone a Burch colposuspension procedure 3–6 (mean 4.5) years earlier and were evaluated retrospectively. The remaining 65 women (group I) had undergone

Table 3. Symptom-free cure rate of group II patients with time

	Time, years			
	3 (n = 56)	4 (n = 42)	5 (n = 32)	6 (n = 25)
Symptom-free cure rate	47 (83.9%)	32 (76.2%)	24 (75%)	17 (68%)

a Burch colposuspension procedure 1–2 (mean 1.5) years earlier and were evaluated prospectively. Patients' characteristics are shown in table 1. Of 65 women in group I, 57 were continent (87.7%). Of 8 women with urinary incontinence, 6 were surgical failures [4 GSI (6.2%), 2 had mixed incontinence (3.1%)] and 2 had detrusor instability (DI, 3.1%). In group I, 10 of 11 women with DI preoperatively were released and only 1 (9.1%) had persistent DI postoperatively. Two women (3.1%) had de novo DI. Of 155 women in group II, 120 were continent (77.4% symptom-free). Of 35 women with urinary incontinence, 30 were surgical failures [19 GSI (12.2%) and 11 mixed incontinence (7.1%)] and 5 (3.2%) had DI. The outcome of the operation at follow-up is shown in table 2. In group II, the percentage of the symptom-free cure rate declined with passing time (table 3).

The procedure was primary in 191 (86.8%) women and secondary for recurrence of incontinence in 29 (13.2%), with 1 having had three and 4 having had two procedures for a total of 35 previous anti-incontinence operations. Anterior repair was the most commonly performed operation (29 anterior repair, 3 Marshall-Marchetti-Krantz and 1 needle suspension). Of the 191 women who had undergone primary surgery, 27 had urinary incontinence (14.1%) while 18 had urinary incontinence (62.1%) of 29 with recurrent surgery. Urinary incontinence was significantly more common in women who had undergone previous anti-incontinence surgery ($p < 0.001$). Of 220 women, 176 (80%) had additional operations: 120 abdominal hysterectomy with or without bilateral salpingo-oophorectomy, 10 tubal ligation, 9 had myomectomy, 3 had ovarian cyst extirpation, and 34 posterior colporrhaphy.

There was a significant difference between the preoperative and postoperative BN location and the BN mobility in group I ($p < 0.001$; table 4). The BN of continent women was higher away from the inferior border of the symphysis pubis and less mobile. There were also significant differences in the BS and Δ BS values between continent women in group I and incontinent patients in group II (table 5).

Table 4. Bladder neck position and mobility in group I (n = 65)

	Preoperative	Postoperative	p
BS	20.17 \pm 3.83	24.54 \pm 3.99	<0.001
Δ BS	20.12 \pm 4.12	6.40 \pm 4.01	<0.001

Table 5. Bladder neck position and mobility in group I women who were anatomically cured and in group I and II women with GSI and mixed incontinence

	Continent (n = 59)	GSI + mixed incontinence (n = 36)	p
BS	24.89 \pm 3.95	21.45 \pm 2.62	<0.001
Δ BS	5.46 \pm 2.35	17.28 \pm 3.40	<0.001

Of all women, 18 (8.2%) had marked cystocele, 32 (14.5%) rectocele and 35 (15.9%) had enterocele at follow-up. Forty-eight women with enterocele had undergone culdoplasty, and 78 women without enterocele had undergone culdoplasty prophylactically. Of 48 women, 7 (14.6%) had marked enterocele, while 7 of 78 women (9%) had marked enterocele at follow-up ($p > 0.05$).

Of 220 women, 6 had dyspareunia (2.7%), 15 had groin or suprapubic pain (6.8%). Five women suffered from voiding difficulty, but none had urinary incontinence. Their total residual urine volumes were <50 ml.

Discussion

The Burch colposuspension operation is one of the most popular and successful operations for GSI caused by BN hypermobility. Earlier cure rates within 3–12 months are high and vary from 87.5 to 100% [3–7]. Studies describing results over longer periods are rare. Success rates after surgery seem to be inversely related to the length of postoperative follow-up [5, 6, 8]. In the present

study, the overall cure rate was 87.7% for 1.5 years and 77.4% for 4.5 years of follow-up. The symptom-free cure rate declined 83.9% for 3, 76.2% for 4, 75% for 5 and 68% for 6 years. Van Geelen et al. [5] reported an objective cure rate after 3 months of 100% and at 1–2 years it was 85%. However, 5 years after the procedure only 75.8% of the women were symptom-free. Thunedborg et al. [6] reported a complete cure rate of 78.6% for 6 years, Kinn [9] reported 78% for 5 years, Eriksen et al. [8] reported 67% for 5 years, Lebret et al. [10] reported 64% for 5 years, Kjolhede and Ryden [11] reported 63% for 6 years and Christensen et al. [12] reported 33%. These earlier and long-term results are comparable with our results. In contrast to these results, Herbertson and Iosif [13] reported a 90.3% cure rate for 9.4 years.

De novo DI and persistence of DI after Burch procedures are controversial. Persistent DI was reported in 15% by Koonings et al. [14], 33% by Eriksen et al. [8], 45% by Sand et al. [15] and 79% by Jorgensen et al. [16]. De novo DI was reported in 8% by Sand et al. [15] and 20% by Jorgensen et al. [16]. We found DI persistence to be 9.1%, while de novo DI was 3.1%. A lower persistence rate of DI and de novo DI may be dependent on our patients who were younger and only one third were postmenopausal. Aging and hormonal status may affect bladder stability negatively [9].

The present study has shown that a previous incontinence operation impairs the results of further incontinence surgery. The cure rate was 85.9% in a primary procedure while it was only 37.9% in secondary surgery. Stanton and Cardozo [7], Kjolhede and Ryden [11] and Christensen et al. [12] reported cure rates lower than our results for secondary surgery: 65, 33 and 33%, respectively. These results emphasize that the critical operation for GSI is the first one.

The criterion for BN mobility during stress was taken as 10 mm by ultrasonographical evaluation [17]. In the present study, the BN was significantly higher away from the inferior border of the symphysis pubis and less mobile in the postoperative period than in the preoperative period (table 3). The BN was also significantly higher and less mobile in continent women than in incontinent ones (table 4). These results support those who claim that Burch colposuspension elevated the BN into the abdominal cavity and stabilized it during stress [5, 18].

The colposuspension procedure seems to aggravate posterior vaginal wall weakness. Enterocele is a significant late complication of the Burch procedure and is reported in 3% by Stanton et al. [19], 8% by Galloway et al. [20], 17% by Kjolhede and Ryden [11] and 26% by

Herbertson and Iosif [13]. In the present study, postoperative enterocele was not significantly different between women who had enterocele and had undergone culdoplasty and women without enterocele who had undergone culdoplasty prophylactically. These results have shown that culdoplasty should only be performed in women who had enterocele preoperatively as recommended by previous studies [3, 9].

Dyspareunia and groin pain were rare complications of the Burch procedure in the late period. Suspension sutures are responsible for groin or suprapubic pain. They pull the anterior vaginal wall up and change the vaginal axis therefore they are responsible for dyspareunia. We found 2.7% dyspareunia and 6.7% groin or/and suprapubic pain. Dyspareunia was reported in 2% by Wang [21], 2.9% by Galloway et al. [20], 3.5% by Eriksen et al. [8] and 4% by Galloway et al. [20]. Galloway et al. [20] and Wang [21] reported postoperative groin/suprapubic pain in 12 and 2.4%, respectively.

In conclusion, the cure rate of Burch colposuspension is satisfactory although it declines a little depending on time. Women who had previous anti-incontinence surgery have more probability of recurrence. The procedure elevates the BN into the abdominal cavity and stabilizes it. Surgical failure is related to inadequate elevation and stabilization of the BN.

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